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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,254	TABIBZADEH, SIAMAK	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-48,54-71 and 74-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *70* is/are allowed.

6)☒ Claim(s) *41-48,54-69,71 and 74-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/05*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *4/7/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 41-48, 54-71,74-80 are pending.

Allowable Subject Matter

1. Claim 70 defines over the prior art of record and is allowed.

Response to Amendment

2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Specification

3. The disclosure is objected to because of the following informalities: The first sentence of the Specification has been amended to recite the phrase "U.S. provisional application Serial No. 60/083,418, filed April 29, 1998, and this applications is a continuation-in –part of US application Serial No. 08/919,421". This phrase is unclear and should be amended to recite ----------and 09/674,254 is a continuation-in –part of US a`pplication Serial No. 08/919,421-----

Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 41, 54 ,61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 3 and 8 of U.S. Patent No. 5,916,751. Although the conflicting claims are not identical, they are not patentably distinct from each other because: The allowed species of method determines the level of ebaf nucleic acid relative to normal levels of ebaf, wherein the level above the normal level is diagnostic of a condition that shows infertility (the presence of cancer, instant claim 61), is diagnostic of the absence of endometrial receptivity (instant claim 54, the presence of cancer defines a condition that is abnormal and does not define endometrial receptivity), and the presence of cancer detects an irregularity in the level of ebaf (instant claim 41), and the instantly claimed methods can detect or determine any level of ebaf, in a bodily fluid in a female animal, and the allowed claim 8 detects ebaf in blood, an endometrial fluid that comprises serum. The allowed species of invention anticipates the instantly claimed genus of methods now claimed.

6. Claim 71, 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,683,156. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species of invention is a protein encoded by a nucleic acid of SEQ ID NO 1 of an endometrial bleeding associated factor (ebaf), and the instantly claimed composition is directed to any ebaf protein encoded by any nucleic acid of any sequence, thus defining a genus of nucleic acids to encode the protein. The protein composition of claim 71 includes a carrier, and the protein composition of claim 79 is included in a container, while the allowed protein of the US 6,683,156 is directed to an isolated protein. The isolated protein of US Pat. 6,683,156 is disclosed and combined with a carrier, specifically phosphate buffered saline, a type of pharmaceutically acceptable carrier (see col. 10, lines 55-56 and line 61 "PBS"), and is also disclosed for formulation into a convenient test, a type of kit "Consequently, applicants believe a simple, cost, effective screening test" is to include the protein of the allowed claims. Therefore it would have been obvious to combine a protein with a pharmaceutically acceptable carrier for the purpose of formulating compositions that maintain the antigenicity of the protein (see '156, col. 10, "purified antigen", reacts with an antibody, in PBS), when combined with a pharmaceutically acceptable carrier and to formulate the protein encoded by a ebaf nucleic acid into kit form to produce a "simple, cost effective screening test". The recited intended use of the instantly

claimed composition or formulation of the protein into a test kit container does not structurally distinguish the composition over the obvious allowed protein composition of claims 1-2 of US Pat. 6,683,156.

7. Claim 80 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,294,662. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed kit composition comprises any oligonucleotide primer or probe of any nucleic acid sequence that can be amplified or is detectable for ebaf, and the allowed claim compositions are specific ebaf nucleic acid sequences that are detectable (see'662,claim 7) or can be amplified in a polymerase chain reaction (cDNA or RNA or DNA,'662, claims 1-6) and the allowed compositions are defined to be reagents for incorporation into a kit test, specifically "Consequently, applicants believe a simple, cost effective screening test (see '662, col. 2, lines 62-63)" . The allowed species anticipates the instantly claimed genus of compositions that comprise the same or equivalent nucleic acids with the recited functionalities. It would have been obvious to formulate the allowed nucleic acids useful as primers and probes into containers for a test kit, in light of the guidance and teaching provided by the Specification of '662, which teaches the need for a simple, cost effective screening test and kits are screening tests that comprise containers formulated for ease of use, the nucleic acids being detectable or amplifiable and would detect the presence or absence of ebaf in a patient sample.

7. Claims 41-48 and 54-63, 64-65, 68, 71, 74-75, 78-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

These claims read on a genus of method that utilize any ebaf nucleic acid from any source or species of animal and therefore includes the utilization of species homologs of SEQ ID NO 1, that encodes the human ebaf protein SEQ ID NO 2 thereof. However, the specification

does not provide adequate written description to support for a genus of species homologs to SEQ ID NO: 1. There is inadequate written description to support claims to kits, compositions, and methods of use of any ebaf nucleic acid or a protein that encodes a protein to which antibodies are made, wherein the nucleic acid is only defined as evidence the functional characteristics of an ebaf molecule.

With reference to species homologues of SEQ ID N0: 1, applicant has provided the polynucleotide of SEQ ID NO 1 and the amino acid sequence SEQ ID NO 2 and therefore provides for nucleic acid degenerates that encode SEQ ID NO 2, but no functional variants or functional analogues have been described for the instantly claimed genus of compositions and methods of use.

Applicant is claiming polynucleotide homologues only by their functionality of encoding ebaf proteins. More than a statement of biological function is required to satisfy the 112, first paragraph written description requirement for a genus of ebaf proteins. See e.g. Amgen Inc. v. Chuzai Pharmaceutical Co. Ltd., 18 U.S.P.Q.Zd 1016, 1027 (CAFC 1991); and Fiers v. Revel, 25 U.S.P.Q.Zd 1601, 1604-05 (CAFC 1993). ln Amgen v. Chuzai, the Court of Appeals for the Federal Circuit stated that "it is not sufficient to define (a DNA) solely by its principal biological property, e.g. encoding of human erythropoietin." Id. at 1021. Rather, what is necessary is that (the applicant) provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims." Id. at 1027. ln these statements, the court has expressly stated that a DNA molecule must be described by means of description other than by naming the encoded protein to satisfy the l 12 first paragraph written description requirement. More recently, the Federal Circuit again took this position. In the case University of California v.

Eli Lillv and Co., 43 U.S.P.Q.Zd 1398, at 1406 (1997), the court stated that defining a cDNA by its function 'tis only a definition of a useful result rather than a definition of what achieves that result." The court also stated that such a description "does not define any structural features commonly possessed by members of the genus (of claimed CDNAS) that distinguish them from others." ld. Thus, it is clear that identification of polynucleotide by naming the polypeptide it encodes is not sufficient. In the present case, the only description that the applicant has provided for species homologues of SEQ ID NO: 1 is that they must also encode ebaf proteins and this requirement is derived from the specification rather than being explicit in the claims). Such a description is clearly insufficient to support the claimed genus of polynucleotide homologues only by their functionality, that of encoding ebaf proteins. More than a statement of biological function is required to satisfy the 35 USC 112 first paragraph, written description requirement for a genus of DNA molecules. See e.g. Amgen lnc. v. Chuzai Pharmaceutical Co. Ltd., 18 U.S.P.Q.Zd 1016, 1027 (CAFC 1991); and Fiers v. Revel, 25 U.S.P.Q.Zd 1601, 1604-05 (CAFC 1993). ln Amgen v. Chuzai, the Court of Appeals for the Federal Circuit stated that "it is not sufficient to define (a DNA) solely by its principal biological property, e.g. encoding of human erythropoietin." Id. at 1021. Rather, what is necessary is that (the applicant) provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims." Id. at 1027. ln these statements, the court has expressly stated that a DNA molecule must be described by means of description other than by naming the encoded protein to satisfy the 35 USC 112 first paragraph written description requirement. More recently, the Federal Circuit again took this position. In the case University of California v. Eli Lillv and Co., 43 U.S.P.Q.Zd 1398, at 1406 (1997), the court stated that defining a CDNA by its function 'tis

only a definition of a useful result rather than a definition of what achieves that result." The court also stated that such a description does not define any structural features commonly possessed by members of the genus (of claimed CDNAS) that distinguish them from others." ld.

Thus, it is clear that identification of a polynucleotide by naming the polypeptide it encodes is not sufficient. In the present case, the only description that the applicant has provided is SEQ ID NO: 1 that encodes an edaf protein and this requirement is derived from the specification rather than being explicit in the claims. The disclosed single species does not provide descriptive support for a highly variable genus; there is clearly insufficient to support the claimed genus of ebaf nucleic acids that encode a genus of ebaf proteins, that are used to generate a genus of ebaf antibodies.

While it may be obvious to those in the art to screen for a gene or protein with similar biological function and evidences changes in the overall nucleic acid or protein amino acid sequence, it is not immediately obvious to those in the art where the changes in nucleic acid or amino acid sequence will be effected.

Bowie et al (See e.g., Bowie et a1., Science 247, page 1306-1310) presents a discussion on the tolerance of proteins to substitutions in the residue sequence. Although the reference is a discussion of protein substitutions, as the present case is concerned with polynucleotides encoding such proteins, the teachings of the reference are equally applicable to the changes associated with functional homologs of the claimed inventions. The reference states that proteins generally accept a wide variety of substitutions in their residue sequence. However, it also states that some residues must not be substituted at all without loss of the proteins function. The reference also states that the effects of such substitutions are, currently, highly unpredictable.

Thus, one skilled in the art would not be able to recognize from the current disclosure that Applicant was in possession of the instantly claimed genus of ebaf nucleic acids that encode ebaf proteins, that will be bound by antibodies raised to the ebaf protein.

As stated above, the Federal Circuit has held that claiming polynucleotides disclosed by their biological function alone is inadequate to meet the written description requirements. In the present case, not only does the application claim additional undisclosed polynucleotides without such support, it further claims reagents that can screen for protein homologs encoded by the polynucleotide, as well as the protein homologs encoded by to both the disclosed and undisclosed polynucleotides based upon functional activity without any specific structure to define where or what the changes are from the disclosed SEQ ID NO 1 that encodes SEQ Id NO

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 41, 45-46,54-56,59,61-63, 64,66, 68, 71, 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Feinberg et al (US Pat. 5,395,825).

Instant claims 41, 43,45-46,54-56,59,61-62, 64,66, 68: Feinberg et al disclose the instantly claimed method of determining the presence or absence of an endometrial irregularity associated with infertility (see Feinberg et al, col. 3, lines 59-64;col. 5, lines 19-22; col. 6, lines 7-9), the method comprising the step of:

Screening a serum or endometrial fluid (see Feinberg et al, "any reproductive bodily fluid or cell type associated with implantation, col. 6, lines 20-22; "*endometrial biopsy*" col. 6, line 19; "*serum*" col. 6, line 17) for the presence of an ebaf protein, and comparing the level to a normal control (see col. 6, lines 22-23; col. 7, lines 49-51;ee col. 7, lines 40-52; col. 7, lines 47-48 "compared to a normal fertile control").

Instant claims 45-46, 55-56: immunohistochemical straining ("cell type", col. 6, line 20, antibodies col. 7, lines 60-66 and col. 5, line 10; monoclonal antibodies col. 8, lines 17-18; "immunologically reactive quantity and activity of functional TGFB)

Instant claim 62-63: endometrial biopsy, infertility, "on the bleeding profile" col. 8, lines 52-53.

Instant claims 64,66, 68: antibodies against TGFB (see col. 7, lines 60-61, TGFB-4, col. 5, lines10).

(**Instant claim 71, 79:** Feinberg et al disclose the instantly claimed invention directed to a contraceptive composition (see col. 7, lines 40-66) that comprises an ebaf protein, specifically TGFB-4 (see col. 5, lines 10-12) together with a pharmaceutically acceptable carrier (see col. 6, lines 45-55 "infusions, gels, or physiological solutions") formulated into kits (see col. 8, lines 58-60 and col. 5, lines 10-12).

1. Feinberg et al anticipates the instantly claimed invention. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

2. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

10. Claims 64, 66, 68, 69 and 71 are rejected under 35 U.S.C. 102(a) as being anticipated by Meno et al (Nature, May 9, 1996).

11. Meno et al disclose the instantly claimed invention directed to:

12. a composition of protein encoded by an ebaf nucleic acid with a pharmaceutically acceptable carrier (cell lysates and conditioned medium containing the ebaf protein expressed into the medium at a "high level") and

13. an isolated antibody (see Fig 2 ledger, epitopes shared with SEQ Id NO 3 and EBAF protein) that will bind to a protein encoded by an ebaf nucleic acid (Meno et al cloned the ebaf nucleic acid in expression vectors and obtained the protein in cell lysates containing conditioned medium) , the antibody being a polyclonal antibody to mouse TGFβ "lefty" protein (see page 151, col. 2, paragraph 4). TGFβ "lefty" protein is another name for EBAF protein (see SWISS-PROT accession number O00292, synonyms). The antibodies of Meno et al anticipates the instantly claimed invention.

14. Claims 64, 66, 68, 69 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Wieczorek et al (July 1995 (chicken TGF-Beta 4).

15. Wieczorek et al disclose the instantly claimed invention directed to a composition of isolated antibodies the specifically bind to a protein encoded by an ebaf nucleic acid (see humoral immune response :Figure 2, "RKDLQ" and "RNVRV"; Table 1, Fragments defined to be TGFB-4 fragments another name for ebaf protein. with a pharmaceutically acceptable carrier (cell lysates and conditioned medium containing the ebaf protein expressed into the medium at a "high level") . The reference also formulated and administered compositions that comprised "a protein encoded by an ebaf nucleic acid", specific chicken ebaf encoded peptides that represented functional epitopes with differing biological functional characteristics (see page 116, col. 2, TGFB-4) .

16. The antibodies and compositions of Wieczorek et al anticipate the instantly claimed invention.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 65, 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meno et al (May 1996).

Meno et al disclose the production of antibodies to specific to a protein encoded by an ebaf nucleic acid, wherein the antibodies were isolated and purified into an affinity purified

monospecific antibody (see page 154, top of page, Fig. 2 ledger "affinity purified" antibodies are monospecific antibodies to the shown epitopes), but differs from the instantly claimed invention by failing to show the monospecific antibody to be a monoclonal antibody.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to produce a monoclonal antibody to a known immunogenic epitope to which a polyclonal antiserum has been produced because monoclonal antibodies define an antigen specific reagent of a uniform population of antibodies with a single binding specificity/affinity and are readily obtained from the continuous hybridoma cell line from which they are produced, and thus can be made readily available without continuous-going immunizations of animals. It would be prima face' obvious, and the person of ordinary skill in the art would have had a reasonable expectation of success of obtaining a monoclonal antibody to an antigen to which a polyclonal antibody has already been made. See In re Erlich, 1988.

19. Claims 74-78 rejected under 35 U.S.C. 103(a) as being unpatentable over Meno et al as applied to claims 64-69 above, and further in view of Foster et al (US Pat. 4,444,879).

See discussion of Meno et al above. Meno et al describe, teach, suggest and show antibodies and immunoassays utilizing the antibodies for the determination of a protein encoded by an ebaf nucleic acid (Left protein) but differs from the instantly claimed invention by failing to show the incorporation of the antibodies into kit form.

Foster et al teach the formulation of immunoassay kit reagents (see Figure 6) that comprise "[C]ontainers of both positive and negative controls and a known standard specimen of Ig for quantitation" in an analogous art for the purpose of detecting a protein in a biological

sample (see col. 6, lines 50-51 and col. 1, line 8) that is a simple, economical and rapid method (see col. 6, lines 4-5).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate the antibodies of Meno et al into the immunoassay kits as taught by Foster in view of the guidance and teaching of the prior art as shown be Foster et al because Foster et al teaches kits to include antibodies (see Foster et al, col. 15, lines 24-26) and teach kits to provide means for carrying out reliable, accurate and safe immunoassay detection/diagnostic assays in medical settings (see Foster et al, col. 5, lines 63-68 and col. 6, lines 1-5).

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining kits that comprise antibodies that bind to a protein encoded by an ebaf nucleic acid as taught Meno et al, because Meno et al teach and show of antibodies (an antisera or monoclonal (see In re Erlich, 1988) that evidence ed specific binding to Lefty, a protein encoded by an ebaf nucleic acid , as well an immunoassay for determination/detection of Lefty, EBAF protein in a biological sample and Foster et al teach the importance of formulation of test kits that comprise the necessary reagents so the kits can be readily used in detecting/diagnosing the presence or absence of a protein analyte in a biological sample. Meno et al in view of Foster et al obviate the instantly claimed invention as now claimed.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

2. Tabibzadeh (US Pat. 6,649,588 (method of treating); and 6,747,004 (method of use) are cited to show methods employing ebaf protein.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
April 7, 2005 and
September 23, 2005

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